

JAN 12 2001

EQUIVALENCE COMPARISON**"510K SUMMARY"**

SUBMITTER: Accelerated Rehab Designs, Inc.
32025 Industrial Park Drive
Pinehurst, Texas 77362
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CONTACT: Randall Potter
DATE: 08/13/99

NAME OF DEVICE: TE-2000 Power Tilt / Power Elevating Seating System

TRADE NAME: TE-2000 Power Tilt / Power Lift Seating System

COMMON NAME: Power Tilt-in-Space Seating System with Power Lift
Center of Gravity, Power Tilt in Space System with Power Lift

CLASSIFICATION NAME: Physical Medicine / Wheelchair, Powered

PRODUCT CODE: ITI

REGULATION No: 890.3860

TYPE: Traditional

SUBSTANCIAL EQUIVALENCE:

Motion Concepts: Power Tilt System with Power Lift

Mechanical Application Designs: Tiltmaster Center of Gravity Power Tilt System with Power Lift

DESCRIPTION: THE ACCELERATED REHAB DESIGNS "TE-2000 POWER TILT / POWER ELEVATING COMBINATION SEATING SYSTEM" IS A CENTER OF GRAVITY DESIGN, AFTERMARKET POWER TILT IN SPACE / POWER LIFT SYSTEM THAT UTILIZES THE WHEELCHAIR MANUFACTURES EXISTING TUBULAR SEAT FRAME, ARMRESTS, FRONT RIGGING, BACK ASSEMBLY AND OPTIONAL ACCESSORIES.

THE WHEELCHAIR BASE AND SEAT FRAMES COMPATABLE FOR INSTALLATION OF THE TE-2000 SYSTEM AT THIS TIME WILL BE:

- INVACARE STORM SERIES WHEELCHAIRS (REAR WHEEL DRIVE)
- INVACARE STORM SERIES WHEELCHAIRS (MID-WHEEL DRIVE)
- INVACARE STORM SERIES WHEELCHAIRS (FRONT WHEEL DRIVE)
- INVACARE RANGER-II WHEELCHAIR (MID-WHEEL DRIVE)
- INVACARE RANGER-II WHEELCHAIR (FRONT WHEEL DRIVE)
- INVACARE PRONTO WHEELCHAIR
- QUICKIE P-320 WHEELCHAIR
- QUICKIE S-424 WHEELCHAIR
- QUICKIE S-525 WHEELCHAIR
- QUICKIE S-626 WHEELCHAIR
- PRIDE JAZZY 1120, 1120-2000, 1170, 1400, 1420 WHEELCHAIRS
- EVEREST & JENNINGS LANCER 2000 WHEELCHAIR
- BRUNO PWC-2200
- BRUNO PWC-2300

THE SYSTEM CONSISTS OF STEEL AND ALUMINUM BRACKETS AND MOUNTING HARDWARE. THE TE-2000 SYSTEM UTILIZES A LINEAR ACTUATOR MANUFACTURED BY LINAK CORPORATION, AND HAS A LOAD CAPACITY OF 750 POUNDS. THE LINAK ACTUATOR HAS AN INTERNAL SAFETY NUT ATTACHED TO THE BALL SPINDLE IN THE CASE OF ACTUATOR FAILURE. THIS SAFETY NUT WILL NOT ALLOW THE SEATING SYSTEM TO TILT BACKWARD ANY FARTHER THAN THE FULL STROKE OF THE ACTUATOR. THIS ELIMINATES THE POSSIBILITY OF THE CLIENT TIPPING OVER BACKWARD DUE TO ACTUATOR FAILURE. THE WHEELCHAIR SEAT FRAME IS ATTACHED TO THE T-2000 SYSTEM MOUNTING HARDWARE BRACKETS AND HARDWARE.

THE TE-2000 INCORPORATES A TOWER LIFT ACTUATOR FROM MOTION SYSTEMS. THE STROKE OF THE LIFT ACTUATOR IN A LIFT / TILT COMBINATION SYSTEM IS 7" IN ORDER TO GIVE THE CUSTOMER THE LOWEST SEAT TO FLOOR HEIGHT POSSIBLE. THE MOTION TOWER ACTUATOR IS BOLTED TO THE WHEELCHAIRS BASE FRAME VIS MOUNTING BRACKETS SPECIFIC TO THE PARTICULAR WHEELCHAIR MODEL. THE TOP OF THE OUTER SHAFT OF THE ACTUATOR IS ALSO STABILIZED TO THE WHEELCHAIRS UPPER FRAME ASSEMBLY FOR MAXIMUM SUPPORT AND STABILITY.

THE TE-2000 SYSTEM IS ACTIVATED BY A DUAL DIRECTION "LOW-AMP" TOGGLE SWITCH WHICH HAS BEEN SPLIT INTO TWO MONO-LEAD JACKS. THIS SPLIT ALLOWS FOR THE TILT TO BE ACTIVATED WITH ONE DIRECTION OF THE TOGGLE SWITCH WHILE THE ELEVATING SEAT IS ACTIVATED BY THE OTHER DIRECTION. INCLUDED IN THE WIRING HARNESS IS A LOW-AMP SWITCH INTERFACE BOX

THAT WILL ACCEPT MOST INDUSTRY WIDE LOW-AMP SINGLE SWITCHES UTILIZING AN 1/8TH INCH MALE MONO JACK LEAD.

AS THE TOGGLE SWITCH IS ACTIVATED IN ONE DIRECTION, THE SEATING SYSTEM WILL BEGIN TO TILT. AS THE SYSTEM IS TILTING, THE SEATING SYSTEM IS ALSO MOVING FORWARD MAINTAINING THE CENTER OF GRAVITY OF THE CLIENT ON THE WHEELCHAIRS BASE FRAME. THIS ALLOWS FOR USE OF SHORTER BASE FRAMES FOR A WIDER RANGE OF INDIVIDUALS. THE HEAVIER, TALLER CLIENT CAN HAVE THE SAME ACCESS AND PERFORMANCE AS THE SMALLER, LIGHTER CLIENT.

THE TE-2000 HAS A STANDARD TILT RANGE OF ZERO TO 50 DEGREES. CUSTOM ANGLES ARE AVAILABLE. THERE IS A MINI-MICRO SWITCH ATTACHED TO THE SYSTEMS MOUNTING HARDWARE THAT RESTRICTS THE CLIENT FROM DRIVING BEYOND 20 DEGREES OF TILT.

WITH THE TILT SYSTEM IN THE DOWN POSITION, ACTIVATION OF THE TOGGLE SWITCH IN THE OTHER DIRECTION WILL ELEVATE THE SEATING SYSTEM. ACTIVATION OF THE SWITCH IN THE SAME DIRECTION WILL LOWER THE ELEVATING SEAT SYSTEM. THE CLIENT MAY NOT ELEVATE AND TILT AT THE SAME TIME. THERE ARE MECHANICAL SWITCHES TO LOCK OUT THE LIFT WHILE TILTED AND LOCK OUT THE TILT WHILE ELEVATED.

THE ACCELERATED REHAB DESIGNS TE-2000 POWER TILT / POWER ELEVATING SEAT SYSTEM HAS NO SOFTWARE BASED COMPONENTS.

INTENDED USE: THE ACCELERATED REHAB DESIGNS, INC T-2000 POWER TILT SEATING SYSTEM IS INTENDED FOR THE CLIENT THAT REQUIRES POSITIONING CHANGES DURING THE COURSE OF THE DAY WITHOUT THE AID OF AN ATTENDANT. THIS COULD BE FOR PRESSURE RELIEF, COMFORT ADJUSTMENTS, AND POSITIONING NEEDS. THE SYSTEM IS ALSO INTENDED TO ALLOW THE CLIENT ACCESS TO ITEMS IN LOCATIONS TOO HIGH TO REACH FROM THE STANDARD WHEELCHAIR HEIGHT. THIS COULD BE CUPBOARDS, FILE CABINETS, DRAWERS, ETC.

TECHNOLOGICAL CHARACTERISTICS: THE TE-2000 SYSTEM UTILIZES THE LINAK ACTUATOR WHICH HAS A PROVEN TRACK RECORD OF PERFORMANCE, AND RELIABILITY. THE SYSTEM MOVES FORWARD ON THE T-2000 MOUNTING HARDWARE VIA A PAIR OF SELF- CLEANING, LINEAR BEARING GUIDES. BY USE OF THESE GUIDES, THERE IS VERY LITTLE RESISTANCE ASSOCIATED WITH THE TILTING OF THE SYSTEM. THE LINEAR BEARINGS ARE MUCH MORE EFFICIENT THAN CAMS, AND OIL LIGHT ROLLER BEARINGS. THIS INCREASES ACTUATOR LIFE, AND REDUCES STRESS AND FATIGUE ON STRUCTURAL COMPONENTS. THE TE-2000 SYSTEM ALSO INCORPORATES A LINEAR TOWER ACTUATOR FROM MOTION SYSTEMS. THIS ACTUATOR IS VERY STRONG AND RELIABLE AND IS ABLE TO HANDLE THE LOADS REQUIRED OF IT. ACCELERATED REHAB DESIGNS ALSO SECURES THE LIFT ACTUATOR AT THE TOP AS WELL AS THE BOTTOM FOR MAXIMUM SUPPORT.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

Mr. Randall Potter
Accelerated Rehab Designs, Inc.
32025 Industrial Park Drive
Pinehurst, Texas 77362

Re: K010011

Trade Name: TE-2000 Power Tilt/Power Elevating Seat Combination System
Regulatory Class: II
Product Code: ITI
Dated: January 1, 2000
Received: January 2, 2000

Dear Mr. Potter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Miriam C. Provost for". The signature is written in dark ink and is positioned above the printed name of the signatory.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: **TE-2000 POWER TILT / POWER ELEVATING SEAT COMBINATION SYSTEM**

Indications For Use:

The "TE-2000 Power Tilt / Power Elevating Seat System" is an aftermarket Power Tilt / Power Lift Seating System utilizing the wheelchair manufactures base frame and seat frame. The Accelerated Rehab Designs seat frame Assembly may also be utilized. The TE-2000 Power Tilt / Power Lift Seating System attaches between the base frame and seat frame of the wheelchair, allowing for the tilting and elevating action of the system upon activation of the Low-Amp Toggle Switch or any alternative low-amp switch that the client may choose to operate. The TE-2000 system has no software based components. The TE-2000 system is appropriate for individuals who require changes in position without the help of an attendant. It is also beneficial to the client for access to objects unreachable from a standard wheelchair height such as cupboards, drawers, and filing cabinets. Power Tilt / Power Elevating Seat Systems are utilized by individuals with a variety of physical disabilities. Some of the indications for use include:

- The reduction of sitting pressure, may prevent Decubitus Ulcers
- Gravity assisted positioning
- Increased sitting stability
- Assistance in feeding, Improved Swallowing
- Increased Respiratory Function
- Decrease Muscle Tone
- Comfort Adjustments
- Work related environment

Accelerated Rehab Designs makes no claims as to the therapeutic effectiveness of the product(s) listed. Accelerated Rehab Designs recommends that an accredited Rehabilitation Therapist and Supplier evaluate all customers of its products.

The above indications for use are identical to those of the Motion Concepts, Mechanical Application Designs, Power Tilt and Power Elevating Seat Systems we are claiming substantial equivalence.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)

OR

Over -The-Counter Use: ✓
(Optional Format 1-2-96)

Revised 11/13/1998

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K00011